Op-Ed

The DOTs strategy

More than just watching patients take their tablets

Anne Fanning
Division of Infectious Diseases
University of Alberta Hospital
Edmonton, Alberta
T6G2B7
Canada

Correspondence to:
a.fanning@ualberta.ca

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DOTs stands for directly observed therapy short course, the curative treatment for tuberculosis. At its core, it involves supervising the patient's swallowing of medication. One cannot have DOTs, however, without a coordinated program with the following components: reliable, widely available smear microscopy diagnosis; an uninterrupted drug supply; recording and reporting of cases and outcome; and, most important, government commitment to assure that necessary resources are available to maintain the program.[1] These 5 elements make up the DOTs strategy, adopted by the World Health Organization, that cures 85% of patients with tuberculosis. Two-thirds of the world's population has no access to DOTs programs.

In high-income countries, discussion about DOTs involves the pros and cons of supervised therapy and whether the 5% of noncompliant patients have a right to refuse treatment. Elsewhere the debate involves how to make the DOTs strategy available to more than the 16% of people who currently have access.[2-5] This discussion asks the far more important question: Does the estimated one-third of the world population, including 6.69 million tuberculosis patients who currently have no access to the DOTs strategy, have a right to expect it?[5]

Studies show that DOTs produces higher treatment completion rates, reduces resistance, results in less need for retreatment and, overall, lowers the rate of tuberculosis.

It was long ago recognized that treatment had to be supervised, as shown in the early British Medical Research Council trials[6,7] and as vigorously promoted by the Denver TB outpatient clinic.[8] The melding of the 5 elements into a national TB program took place in Tanzania in a partnership between that government, Karel Styblo, and the International Union Against Tuberculosis and Lung Disease.[9] The subsequent adoption and marketing of the DOTs strategy by WHO and the efforts of the International Union Against Tuberculosis and the Royal Netherlands Tuberculosis Association have increased to over 100 the number of countries committed to the DOTs strategy and have increased the number of cases covered by the strategy to over a million.[2,4]

Noncompliance by doctors or patients with the standard 6-month treatment regimen is the commonest cause of treatment failure.[10,11] Studies show that DOTs produces higher treatment completion rates, reduces resistance, results in less need for retreatment and, overall, lowers the rate of tuberculosis.[12] Debate continues over selective versus universal application of DOTs. In favor of its universal application is the argument that determination of nonadherence is fraught with difficulty.[13] Those who use selective criteria apply social factors such as homelessness and unemployment, or the medical imperative of drug resistance, claiming that universal DOTs would be labor intensive, expensive, and unnecessary.[12] Those who advocate universal application of the strategy show that reallocation of resources achieves savings over the costs of failed treatment, spread of disease, and drug resistance.[12]

The legal arguments supporting the right to refuse treatment are negated by the need to protect the public's health from tuberculosis, which is spread to innocent bystanders in the air.[14] In 1993, the New York City Code of Health was amended to empower the commissioner of health to compel a person to be examined for suspected tuberculosis, to receive treatment for tuberculosis, or to be detained for treatment. Only 4% of 8000 patients who failed to adhere to DOTs in the community had to be detained for treatment. The graduated application of coersive measures, as well as the right of appeal, must be shown before resorting to confinement for treatment.[15] The right to refuse treatment is excepted in tuberculosis, however, because of its airborne transmission, DNA fingerprint evidence of casual spread, and the emergence of multidrug-resistant tuberculosis after poor treatment. The ethical right to detain to prevent transmission of infection is also supported in biblical and Talmudic law.[16]

In high-income countries, rates of tuberculosis are low and good outcome after treatment is assumed. But as in New York City in the 1980s,[10] unless surveillance is maintained, complacency can lead to a poor outcome. Therefore, in 1993 the US Advisory Council for the Elimination of Tuberculosis recommended directly observed therapy if completion rates were less than 90%. In that year, 34% received DOTs and 91.2% of them completed treatment.[17] In Canada, although DOTs is recommended,[18] its application varies from one province to the next.

The World Health Organization maintains a worldwide surveillance system of the application of the DOTs strategy, measuring indicators for each of the 5 components. The 1999 global tuberculosis report of 1997 cases[4]

identified 102 "DOTs countries" but only 59 with implementation throughout. Overall, 173 countries reported cases, for a total of 3.37 million or 37% detected of the 7.96 million estimated. Only 16% of the estimated number of smear-positive cases were reported from DOTs strategy programs. Where these programs exist, cure rates usually exceed the global target of 85%, but the case detection rate is well below the target of 70%.[4] There is a trend toward improved cure and detection rates in the 22 high-burden countries, which have 80% of the cases, but few reach the global targets.

The debate over the right of the 5% of people with tuberculosis to refuse DOTs must not distract us from the larger human rights issue that one third of the world's population has no access to the DOTs strategy.

Some remarkable successes have been achieved. In Bangladesh and Peru, for example, the implementation of the DOTs strategy has expanded rapidly and cured over 85% of the people treated.[4] In sub-Saharan Africa, however, in spite of well-executed countrywide programs, rates continue to rise through HIV/tuberculosis coinfection. Here the strategy cannot contain the rising rates but can prevent the emergence of untreatable drug-resistant disease.[19]

The debate over the right of 5% of people with tuberculosis to refuse DOTs must not distract us from the larger human rights issue that one third of the world's population[2] has no access to the DOTs strategy. Although the world's nations declared "Health for all by the year 2000" as the goal of the Alma Ata Primary Health Conference of 1978,[20] the entrenched inequalities between rich and poor countries and communities within them make equal access to the DOTs strategy unattainable. WHO's new director-general, Gro Harlen Brundtland, addressing the African region of WHO in April 1999, noted the uneven burden of disease, with 90% occurring in regions having 10% of the resources. Brundtland asked for partners in a "new universalism," assuring access to quality care.[21] This is the bioethical challenge of tuberculosis: to give to the 6.69 million tuberculosis cases who now have no access to the DOTs strategy the right to accept or refuse it.

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